VITTI-PURE

VITTI-PURE INFORMATION & PREPARATION INSTRUCTIONS

VITTI-PURE is a minimally manipulated, DMSO free, bio-ethical human umbilical cord procured product from donated human tissue manufactured under the AATB and FDA HCT/P 361 guidelines for homologous use in clinical settings. Our proprietary process is absent of harmful enzymes and chemicals to preserve structural integrity.

- ✓ This tissue was prepared from a donor determined to be eligible based on the results of screening and testing.
- ✓ This tissue allograft is determined to be suitable and released for human transplant use.

INSTRUCTIONS FOR USE:

VITTI-PURE is an umbilical cord derived tissue product from bio-ethically donated human tissue intended for homologous use. VITTI-PURE is derived from non-conduit structural tissue and not applicable for any conduit applications.

These recommendations are designed to serve only as general guidelines. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

1. When opening the package, use aseptic technique.
2. Look to ensure the product is intact, and the packaging has not been compromised.
3. Only the product within the vial is aseptic. The outside of the vial is not aseptic. Do not sterilize the contents of the vial.
4. Use immediately once the vial is thawed.
5. By opening the vial the seal is broken. Open the vial aseptically as well as apply the tissue aseptically through transplantation, implantation, or transferring, if appropriate, or otherwise discard the tissue. Do not let the tissue dehydrate.

Each vial of VITTI-PURE is intended for use on a single patient on one occasion. Discard any unused portions of VITTI-PURE per institutional procedures. Product must be used prior to the expiration date on the product container.

CONTRAINDICATIONS

VITTI-PURE is contraindicated in patients with a known hypersensitivity to VITTI-PURE. These products should not be used in areas of active infection, or in patients who likely have active infections or conditions that may cause a substantial risk to the patient.

WARNINGS

If symptoms arise such as, nausea, fever, chills, dark urine, chest and lower back pain, consult your physician immediately. No adverse clinical reactions to this tissue product have been reported. Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to Vitti Labs. Even though there may only be residual trace amounts on the tissue, this tissue has been exposed to alcohol. If a disease transmission complication from Vitti Labs use is confirmed to be fatal, report immediately to the State Health Department and Vitti Labs. If a patient has an adverse reaction related to the use of Vitti Labs, discontinue use immediately.

VITTILABS.com

VITTI PURE

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Label 220.109.LBLVP02

GMP CERTIFIED

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